EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to L-tyrosine and contribution to normal synthesis of catecholamines (ID 1928), increased attention (ID 440, 1672, 1930), and contribution to normal muscle function (ID 1929) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

EFSA Publication

Link to article, DOI:
10.2903/j.efsa.2011.2270

Publication date:
2011

Document Version
Publisher's PDF, also known as Version of record

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to L-tyrosine and contribution to normal synthesis of catecholamines (ID 1928), increased attention (ID 440, 1672, 1930), and contribution to normal muscle function (ID 1929) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to L-tyrosine and contribution to normal synthesis of catecholamines, increased attention, and contribution to normal muscle function. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent, which is the subject of the health claims, is L-tyrosine. The Panel considers that L-tyrosine is sufficiently characterised.

Contribution to normal synthesis of catecholamines

The claimed effect is "L-tyrosine is the ultimate precursor of neurotransmitters". The target population is assumed to be the general population. In the context of the references provided, the Panel assumes that the claimed effect relates to the normal synthesis of catecholamines. The Panel considers that contribution to normal synthesis of catecholamines is a beneficial physiological effect.

L-Tyrosine is the starting point for the synthesis of all catecholamines.

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[1] On request from the European Commission, Question No EFSA-Q-2008-1227, EFSA-Q-2008-2408, EFSA-Q-2008-2661, EFSA-Q-2008-2662, EFSA-Q-2008-2663, adopted on 25 March 2011.

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[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims : Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Mental/Nervous System: Jacques Rigo, Astrid Schloerscheidt, Barbara Stewart-Knox, Sean (J.J.) Strain, and Peter Willatts.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to L-tyrosine and contribution to normal synthesis of catecholamines (ID 1928), increased attention (ID 440, 1672, 1930), and contribution to normal muscle function (ID 1929) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2270. [16 pp.]. doi:10.2903/j.efsa.2011.2270. Available online: www.efsa.europa.eu/efsajournal

The Panel concludes that a cause and effect relationship has been established between the consumption of L-tyrosine in a protein adequate diet and contribution to normal synthesis of catecholamines.

No evidence has been provided that the protein supply in the diet of the European population is not sufficient to fulfil this function of the amino acid.

In order to bear the claim a food should be at least a source of protein as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

Increased attention

The claimed effects are "involved in energy production", "helps to support cognitive performance during exposure to environmentally adverse conditions", and "cognitive function/mental health". The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to increased attention. The Panel considers that increased attention is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the two studies from which conclusions could be drawn for the substantiation of the claim showed no effects of L-tyrosine on attention endpoints compared to placebo.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of L-tyrosine and increased attention.

Contribution to normal muscle function

The claimed effect is "essential for muscle function and for optimal muscle contraction". The target population is assumed to be the general population. The Panel considers that contribution to normal muscle function is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of L-tyrosine and contribution to normal muscle function.

KEY WORDS

Tyrosine, catecholamines, attention, muscle function, health claims.

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[4] submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out[5]. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is L-tyrosine.

L-Tyrosine is a conditionally indispensable amino acid which occurs naturally in foods, mainly as part of proteins. Dietary L-tyrosine is provided by mixed dietary protein intakes from different sources; it can also be consumed in the form of food supplements. The content of L-tyrosine in foods can be measured by established methods.

The Panel considers that the food constituent, L-tyrosine, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Contribution to normal synthesis of catecholamines (ID 1928)

The claimed effect is "L-tyrosine is the ultimate precursor of neurotransmitters". The Panel assumes that the target population is the general population.

In the context of the references provided, the Panel assumes that the claimed effect relates to the normal synthesis of catecholamines.

The Panel considers that contribution to normal synthesis of catecholamines is a beneficial physiological effect.

2.2. Increased attention (ID 440, 1672, 1930)

The claimed effects are "involved in energy production", "helps to support cognitive performance during exposure to environmentally adverse conditions", and "cognitive function/mental health". The Panel assumes that the target population is the general population.

[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

[5] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effects refer to increased attention (concentration), which is a well defined construct and which can be measured by validated psychometric tests.

The Panel considers that increased attention is a beneficial physiological effect.

2.3. Contribution to normal muscle function (ID 1929)

The claimed effect is "essential for muscle function and for optimal muscle contraction". The Panel assumes that the target population is the general population.

The Panel considers that contribution to normal muscle function is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Contribution to normal synthesis of catecholamines (ID 1928)

L-Tyrosine is the starting point for the synthesis of all catecholamines. L-Tyrosine is hydroxylated to form dihydroxy-L-phenylalanine (also known as levodopa or L-dopa) via the enzyme tyrosine hydroxylase. In dopaminergic neurons, L-dopa is metabolised to dopamine by means of the enzyme dopa decarboxylase. In noradrenergic nerve cells and in the adrenal medulla, dopamine is transformed to noradrenaline via the enzyme dopamine β-hydroxylase. Noradrenaline can then be transformed into adrenaline by the addition of a methyl group through the action of phenylethanolamine-N-methyltransferase (Friedhoff and Silva, 2002).

The Panel concludes that a cause and effect relationship has been established between the consumption of L-tyrosine in a protein adequate diet and contribution to normal synthesis of catecholamines. However, no evidence has been provided that the protein supply in the diet of the European population is not sufficient to fulfil this function of the amino acid.

3.2. Increased attention (ID 440, 1672, 1930)

The references provided for the scientific substantiation of the claim included textbooks, a publication from an authoritative body, a popular science book and narrative reviews, which mostly reported on tyrosine as a treatment for depression, and on tyrosine toxicity, and did not provide original data for the scientific substantiation of the claimed effect. Some human studies reported on trials in patients groups with narcolepsy/catalepsy, major depression, attention-hyperactivity disorder and phenylketonuria. The Panel considers that the evidence provided does not establish that results obtained in studies on subjects with these disorders can be extrapolated to the general population with regard to attention. Other references were a human study which did not consider a relevant endpoint (but rather covered the rate of tyrosine metabolism) and *in vitro/ex vivo* studies reporting on aspects (e.g. the properties of the precursor pathway, and the purification and properties of tyrosine transaminase) unrelated to the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

In a double-blind, placebo-controlled study (Deijen and Orlebeke, 1994), the effect of a combination of tyrosine (100 mg/kg body weight) and vitamin B6 (10 mg) on cognitive function was investigated in 16 healthy young male and female subjects under stress conditions (90 dB noise). The Panel considers that no conclusions can be drawn from a study using a combination of tyrosine and vitamin B6 on the effect of L-tyrosine alone.

Three human intervention studies (Banderet and Lieberman, 1989; Neri et al., 1995; Thomas et al., 1999) investigated the effects of L-tyrosine ingestion on cognitive function under various levels of stress conditions.

In the double-blind placebo-controlled study by Banderet and Liebermann (1989), 23 males (18-20 years) underwent two stressor conditions (15°C/4200 m altitude pressure and 15°C/4700 m altitude pressure) and a control condition (22°C/550 m altitude) after ingesting either tyrosine (2 doses of 50 mg/kg body weight) or placebo (not described). Stressors and control condition were applied for 4.5 hours each with a minimum of 48 hours between sessions. Test sessions started at 7.00 am and the treatment was provided at 7.20 am and 8.00 am. Behavioural testing, which started 1 h 20 min after tyrosine/placebo ingestions, included a range of cognitive tests assessing vigilance (choice reaction time task) and attention (sustained attention task, dual vigilance task) along with multiple other endpoints. Analysis was restricted to participants who showed an effect of the stressor (i.e. if differences in scores under stressor conditions and placebo condition were greater than group mean difference). However, no information was available on the number of participants who entered the analysis. The Panel notes that the placebo was not described and that insufficient information was available on the statistical analyses performed. The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claim.

In the randomised, double-blind, placebo-controlled, parallel study by Neri et al. (1995), the effect of tyrosine was assessed in 20 male subjects during an episode of continuous night time work (13 h test duration during the night, from 19.30 pm to 8.20 am). Subjects were submitted to nine experimental blocks of 90 min, separated by 40 min breaks during which they were provided with caffeine-free snacks (composition not described). At 1.30 am and 3.00 am, tyrosine (2 doses of 75 mg/kg body weight, n=10) or placebo (corn starch, 2 doses of 75 mg/kg body weight, n=10) were provided with approximately 113 g of banana yogurt. The testing consisted of a selective attention task (dichotic listening) along with other cognitive endpoints. As an additional stressor, subjects were exposed to a low-frequency 70 dB noise during the tests. Performance on all tasks deteriorated steadily through the night. Differences between groups were not statistically significant for the dichotic listening task. The Panel notes that this study does not show an effect of the consumption of L-tyrosine on attention endpoints.

In a cross-over, double-blind study, Thomas et al. (1999) administered, in a random order, L-crystalline tyrosine (150 mg/kg body weight) and placebo (7 g microcrystalline cellulose) with 70 g apple sauce to 20 young healthy male and female subjects (age range 20-38 years) to investigate the effects of tyrosine ingestion on performance under mild stress conditions. Cognitive testing began 60 minutes post-ingestion and was administered either in a multi-tasking environment (mild stress condition) or in a simple task environment. In the multi-tasking environment subjects were required to simultaneously perform a Sternberg Memory Task (working memory task), an arithmetic task (addition of numbers), a visual monitoring task and an auditory monitoring task (both sustained attention tasks). In the simple task environment, participants were given the Sternberg task and the visual monitoring task only. Differences between groups were not statistically significant for the visual monitoring task and the auditory monitoring task. The Panel notes that this study does not show an effect of the consumption of L-tyrosine on attention endpoints.

In weighing the evidence, the Panel took into account that the two studies from which conclusions could be drawn for the scientific substantiation of the claim showed no effects of L-tyrosine, compared to placebo on attention endpoints.

The Panel concludes that a cause and effect relationship has not been established between the consumption of L-tyrosine and increased attention.

3.3. Contribution to normal muscle function (ID 1929)

Among the references provided, two references were textbooks on the biochemistry of smooth muscle which did not provide original data for the scientific substantiation of the claim. One human study and one *in vitro* study were unrelated to the claimed effect (e.g. phenylalanine metabolism, and activity of tyrosine hydroxylase from beef adrenal medulla). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

One human study investigated the use of L-tyrosine in the treatment of Parkinson's disease (Lemoine et al., 1989). The Panel considers that the evidence provided does not establish that results obtained in studies on patients with Parkinson's disease can be extrapolated to the general population with regard to normal muscle function.

The Panel concludes that a cause and effect relationship has not been established between the consumption of L-tyrosine and contribution to normal muscle function.

4. Panel's comments on the proposed wording

4.1. Contribution to normal synthesis of catecholamines (ID 1928)

The Panel considers that the following wording reflects the scientific evidence: "L-Tyrosine contributes to normal synthesis of catecholamines".

5. Conditions and possible restrictions of use

5.1. Contribution to normal synthesis of catecholamines (ID 1928)

The Panel considers that in order to bear the claim a food should be at least a source of protein as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, L-tyrosine, which is the subject of the health claims, is sufficiently characterised.

Contribution to normal synthesis of catecholamines (ID 1928)

- The claimed effect is "L-tyrosine is the ultimate precursor of neurotransmitters". The target population is assumed to be the general population. In the context of the references provided, it is assumed that the claimed effect relates to the normal synthesis of catecholamines. Contribution to normal synthesis of catecholamines is a beneficial physiological effect.

- A cause and effect relationship has been established between the consumption of L-tyrosine in a protein adequate diet and contribution to normal synthesis of catecholamines.

- No evidence has been provided that the protein supply in the diet of the European population is not sufficient to fulfil this function of the amino acid.

- The following wording reflects the scientific evidence: "L-tyrosine contributes to normal synthesis of catecholamines".

- In order to bear the claim a food should be at least a source of protein as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

Increased attention (ID 440, 1672, 1930)

- The claimed effects are "involved in energy production", "helps to support cognitive performance during exposure to environmentally adverse conditions", and "cognitive function/mental health". The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, it is assumed that the claimed effects refer to increased attention (concentration). Increased attention is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of L-tyrosine and increased attention.

Contribution to normal muscle function (ID 1929)

- The claimed effect is "essential for muscle function and for optimal muscle contraction". The target population is assumed to be the general population. Contribution to normal muscle function is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of L-tyrosine and contribution to normal muscle function.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1227, EFSA-Q-2008-2408, EFSA-Q-2008-2661, EFSA-Q-2008-2662, EFSA-Q-2008-2663). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/article13.htm.

REFERENCES

Banderet LE and Lieberman HR, 1989. Treatment with tyrosine, a neurotransmitter precursor, reduces environmental stress in humans. Brain Research Bulletin, 22, 759-762.

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Lemoine P, Robelin N, Sebert P and Mouret J, 1989. La L-tyrosine: traitement au long cours de la maladie de Parkinson. Comptes rendus de l'Académie des sciences. Série 3, Sciences de la vie, 309, 43-47.

Neri DF, Wiegmann D, Stanny RR, Shappell SA, McCardie A and McKay DL, 1995. The effects of tyrosine on cognitive performance during extended wakefulness. Aviation Space and Environmental Medicine, 66, 313-319.

Thomas JR, Lockwood PA, Singh A and Deuster PA, 1999. Tyrosine improves working memory in a multitasking environment. Pharmacology, Biochemistry and Behavior, 64, 495-500.

APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[6] (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

a) the role of a nutrient or other substance in growth, development and the functions of the body; or

b) psychological and behavioural functions; or

c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[7]

Foods are commonly involved in many different functions[8] of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

[6] OJ L12, 18/01/2007
[7] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[8] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

(a) the claimed effect of the food is beneficial for human health,

(b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),

(c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,

(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity

consumed.

- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to L-tyrosine, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
440	Tyrosine	Helps to support cognitive performance during exposure to environmentally adverse conditions Clarification provided Cognitive and mental performance: Tyrosine is necessary to mantain physical and mental activity specially in situations of high increased requierements.	Tyrosine helps maintain mental focus and performance during exposure to environmentally adverse conditions Tyrosine limits mental fatigue during exposure to environmentally adverse conditions.
	Conditions of use – 100 mg per kilogram of bodyweight 40-80 minutes prior to testing (1) – Tagesdosis L-Tyrosin: 500 mg–Erwachsene – > 500 mg / Tag		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1672	Tyrosine	Cognitive function/Mental health Clarification provided Cognitive function/Mental health. Cognitive and mental performance: Tyrosine is necessary to mantain physical and mental activity specially in situations of high increased requirements.	Helps maintain physical and mental concentration in cases of temporary stress
	Conditions of use – > 500 mg / Tag – Gesamtbevölkerung,–4 mg pro Tag		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1928	L-Tyrosine	L-tyrosine is the ultimate precursor of neurotransmitters	Essential component of almost all proteins in the body.
	Conditions of use – From dietary sources or supplementation		
	No clarification provided by Member States		

ID	Food or Food constituent	Health Relationship	Proposed wording
1929	L-Tyrosine	Essential for muscle function and for optimal muscle contraction	Essential for the natural formation of dopamine, required for normal muscle function and contraction
	Conditions of use – The daily requirement of L-Tyrosine is approximately dependent on weight, 1000 mg per day for people that weigh 50kg, rising to 2000mg per day for people that weigh 100kg		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1930	L-Tyrosine	Involved in energy production Clarification provided Improves focus/attention	Provides energy
	Conditions of use – From dietary sources or supplementation		